Guidance for Industry

Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

Small Entity Compliance Guide

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to http://www.regulations.gov. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. All comments should be identified with Docket No. FDA-2014-D-0917.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m.

Additional copies are available online at http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to Food and Drug Administration, Center for Tobacco Products, Document Control Center, ATTN: Office of Small Business Assistance, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

July 2014

Table of Contents

Contains Nonbinding Recommendations

Guidance for Industry[1]

Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

Small Entity Compliance Guide

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended to help small businesses understand and comply with FDA's requirements for the submission of information needed to calculate the amount of user fees owed by each domestic manufacturer or importer of tobacco products under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Domestic manufacturers and importers of tobacco products must submit the information to FDA beginning October 2014. FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance was prepared by the Office of Management and Office of Regulations in the Center for Tobacco Products at FDA.

II. BACKGROUND

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was enacted on June 22, 2009 (Public Law 111-31), amending the FD&C Act and providing FDA with the authority to regulate tobacco products. Included in FDA's authority is the authority to assess and collect user fees.

Section 919(a) of the FD&C Act requires FDA to, in accordance with that section, "assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products" subject to the tobacco product provisions of the FD&C Act (chapter IX of the FD&C Act). The total amount of user fees for each fiscal year is specified in section 919(b)(1) of the FD&C Act, and under section 919(a) we are to assess and collect one-fourth of that total each quarter of the fiscal year. The FD&C Act provides for the total quarterly assessment to be allocated among classes of tobacco products. The class allocation is based on each tobacco product class' volume of tobacco products removed[2] into commerce. Within each class of tobacco products, an individual domestic manufacturer or importer is assessed a user fee based on its market share for that tobacco product class.

In the *Federal Register* of May 31, 2013 (78 FR 32581), FDA issued a notice of proposed rulemaking (NPRM) to add 21 CFR part 1150 to require domestic tobacco product manufacturers and importers to submit to FDA information needed to calculate the amount of user fees to assess each domestic manufacturer and importer under the FD&C Act. In the *Federal Register* of July 10, 2014 (79 FR 39302), FDA published the final rule, codified at 21 CFR part 1150.

III. QUESTIONS AND ANSWERS

A. Who must submit information to FDA?

The final rule applies to domestic manufacturers and importers of four classes of tobacco products: cigarettes, snuff, chewing tobacco, and roll-your-own tobacco.[3]

[2] Removal is defined at 26 U.S.C. 5702 as "the removal of tobacco products or cigarette papers or tubes, or any processed tobacco, from the factory or from internal revenue bond under section 5704, as the Secretary [of Treasury] shall by regulation prescribe, or release from customs custody, and shall also include the smuggling or other unlawful importation of such articles into the United States."

[3] Section 919(b)(2)(B) also includes cigars and pipe tobacco, but these classes of tobacco products are not currently subject to FDA's regulation under chapter IX of the FD&C Act. FDA intends to further explore issues related to user fee assessments on tobacco products that may be deemed subject to chapter IX of the FD&C Act by soliciting public comment. FDA will make any appropriate changes to the user fee regulations in a new rulemaking.

B. What information must be submitted to FDA by domestic tobacco product manufacturers and importers?

Each domestic manufacturer and importer must submit the following information and documents to FDA:

- Its name and the mailing address of its principal place of business;
- The name and a telephone number, including area code, of an office or individual that FDA may contact for further information;
- The email address and postal address for receipt of FDA notifications;
- Its Alcohol and Tobacco Tax and Trade Bureau (TTB) Permit Number(s);
- Its Employer Identification Number(s) (EIN);
- For each TTB tobacco permit:
    - The units of product (i.e., number of sticks for cigarettes and pounds for other tobacco products), by class, removed and not tax exempt for the prior month and
    - The Federal excise tax paid, by class, for such removal;
- If the domestic manufacturer or importer did not remove any amount of tobacco product, it must report that no tobacco product was removed into domestic commerce;
- Certified copies of the returns and forms that relate to:
    - The removal of tobacco products into domestic commerce (as defined by section 5702 of the Internal Revenue Code of 1986); and
    - The payment of the Federal excise taxes imposed under chapter 52 of the Internal Revenue Code of 1986.

(§ 1150.5(b))

This information is currently submitted on TTB Forms 5210.5, 5000.24, and 5220.6 and Customs CBP Form 7501.

C. When must this information be received by FDA?

Beginning in October 2014, this information must be received by FDA by the 20th of each month. The information must be submitted on a monthly basis, even in months when no tobacco product is removed into domestic commerce. (See § 1150.5(a).)

D. How must this information be submitted to FDA?

Domestic manufacturers and importers must use Form FDA 3852 and attach copies of the appropriate supporting TTB and CBP forms (currently TTB Forms 5210.5, 5000.24, and 5220.6 and CBP Form 7501). This form is available online and in paper form. (See § 1150.5.)

Submit Form FDA 3852 and supporting documents to FDA by mail:

Food and Drug Administration,
Center for Tobacco Products,

Document Control Center,
ATTN: OM, Division of Financial Management, User Fee Team
Building 71, Room G335
10903 New Hampshire Avenue,
Silver Spring, MD 20993-0002

electronically: TOBACCOUSERFEES@fda.hhs.gov, or

by fax: 301-595-1429 or 301-595-1430.

E. How will FDA allocate the total assessment among the classes of tobacco products for each quarter of a fiscal year?

FDA will calculate the percentage shares for each class as follows:

- FDA will multiply the units of product removed and not tax exempt for the most recent full calendar year by the 2003 maximum Federal excise tax rate for that applicable class or subclass (class dollar figure).
- FDA will total the class dollar figures for all tobacco classes for the most recent full calendar year (total dollar figure).
- FDA will divide the class dollar figure by the total dollar figure to determine the percentage share for each class.
- FDA will calculate the allocation for each class of tobacco products by multiplying the percentage share for each class by the total assessment.

(§ 1150.7(a))

F. How will FDA calculate the assessment owed by each domestic manufacturer or importer for each quarter?

The assessment for each class of tobacco products is allocated among the domestic manufacturers and importers in that class, so that each domestic manufacturer's or importer's assessment is proportional to its percentage share within that class.

For each class of tobacco products, FDA will calculate the percentage share for each domestic manufacturer and importer by dividing the Federal excise taxes that it paid for the class for the prior quarter by the total excise taxes that all domestic manufacturers and importers paid for the class for that same quarter. If the percentage share calculated for a domestic manufacturer or importer is less than 0.0001 percent, the manufacturer or importer does not have to pay an assessment. Within each class of tobacco products, the assessment owed by a domestic manufacturer or importer for the quarter is the quarterly class allocation multiplied by the domestic manufacturer's or importer's percentage share for that class of tobacco products. (See § 1150.9(a).)

G. Will FDA make adjustments to individual domestic manufacturer or importer assessments?

Yes. Annually, FDA will make any necessary adjustments to individual domestic manufacturer or importer assessments if needed to account for any corrections (e.g., to include domestic manufacturers or importers that were not included in a relevant assessment calculation) (§ 1150.9(b)).

H. When will FDA notify each domestic manufacturer and importer of the amount of the quarterly assessment?

FDA will notify each domestic manufacturer and importer of the amount of the quarterly assessment no later than 30 calendar days before the end of each fiscal year quarter (§ 1150.11(a)).

I. What information will be included in the notification from FDA?

The notification sent to each domestic manufacturer and importer will include the following:

- The amount of the quarterly assessment and the date that payment of the assessment must be received by FDA;
- Class assessment information;
- Domestic manufacturer or importer assessment information;
- Any adjustments FDA has made under § 1150.9(b);
- The manner in which assessments are to be remitted to FDA;
- Information about the accrual of interest if a payment is late; and
- Information regarding where to send a dispute and when it needs to be sent.

(§ 1150.11(b))

J. When and how must payment of assessments be submitted to FDA?

Payment of an assessment must be received by FDA no later than the last day of each fiscal year quarter. The payment must be in U.S. dollars and submitted to FDA in the manner specified in the notification. (See § 1150.13.)

K. Can a domestic manufacturer or importer dispute an FDA assessment?

Yes, a domestic manufacturer or importer can dispute an FDA assessment but must still pay the assessment (§ 1150.13(e)). Section 1150.15 outlines the dispute process.

L. What is the penalty for failure to pay an assessed user fee?

A tobacco product is deemed adulterated under section 902(4) of the FD&C Act (21 U.S.C. 387b(4)) if the domestic manufacturer or importer fails to pay a user fee by the later of the following: the date the assessment is due, 30 days from the date FDA sent notification of the amount owed, or 30 days after final Agency action on a resolution of any dispute about the amount of the fee. (§ 1150.17(a))

M. What are the penalties for failure to report the information required by § 1150.5?

A tobacco product is deemed adulterated under section 902(4) of the FD&C Act if the domestic manufacturer or importer fails to report the information required by § 1150.5 to calculate assessments. Failure to report the information is also a prohibited act under section 301(e) of the FD&C Act (21 U.S.C. 331(e)). (See § 1150.17(b)-(c).)

N. Are there penalties related to the submission of false information under § 1150.5?

Yes. Information submitted under § 1150.5 is subject to 18 U.S.C. 1001 and other appropriate civil and criminal statutes (§ 1150.17(d)).

O. When does this rule become effective?

This rule becomes effective on August 11, 2014, which is 30 days after the rule published in the *Federal Register* (79 FR 39302). However, as explained in section III.C, the first submission of required information will be due on October 20, 2014.

P. Will FDA provide assistance for small businesses seeking additional information about this rule?

FDA's Center for Tobacco Products has established an Office of Small Business Assistance in an effort to help small businesses access up-to-date information and comply with the requirements of the Tobacco Control Act. CTP's Office of Small Business Assistance can be reached at SmallBiz.Tobacco@fda.hhs.gov or at 1-877-CTP-1373 (1-877-287-1373), Monday-Friday, 9:00 a.m. – 4:00 p.m.